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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,244	01/28/2005	Peter Carmeliet	DECLE70.003APC	9196

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EXAMINER	
CHONG, KIMBERLY	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/502,244	CARMELIET ET AL.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/22/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 3-10, in the reply filed on 01/20/2006 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are drawn to a method of screening for molecules for the treatment of pathological angiogenesis comprising exposing prominin-1 or nucleic acids encoding prominin-1 to at least one molecule whose ability to suppress or prevent pathological angiogenesis is sought to be determined, determining binding or hybridizing of said molecule and monitoring said pathological angiogenesis when administering said molecules as a **medicament**. The claims are further drawn to a method of screening for the treatment of pathological angiogenesis comprising identifying molecules that inhibit the expression and/or activity of prominin-1 and monitoring said pathological angiogenesis when administering said molecules as a **medicament**. The use of the term **medicament** implies that the compounds activity is

known (i.e. it has been determined to be a medicament for angiogenesis). It is unclear how the claims can be drawn to screening for compounds for an activity when the context of the claim implies that the activity is already known?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Majka et al. (cited on PTO form 892 filed 12/19/2005) and evidenced by Peichev et al. (cited on PTO form 1449 filed 7/22/2004).

The instant claims are drawn to a method of screening for molecules for the treatment of pathological angiogenesis comprising exposing prominin-1 or nucleic acids encoding prominin-1 to at least one molecule and determining binding or hybridizing of said molecule and monitoring said pathological angiogenesis.

Majka et al. teach a method of determining the biological effect of AC133 (also called prominin) comprising administering an antisense oligonucleotide molecule to CD34+ cells expressing AC133 and determining the hybridization of the antisense oligonucleotide to the nucleic acid expression AC133 (see page 58 and Figure 4). Majka et al. teach exposing cells expressing AC133 to antibody against AC133 and measuring the binding of the antibody to AC133 in a FACS assay (see Figure 1)

wherein the antibody is immobilized on beads (see page 54 and Figure 1). Majka et al. further teach monitoring of the CD34+ cells, expressing AC133, ability to form haemotopoietic colonies after treatment with an antisense oligonucleotide targeted to AC133 (see page 58 and Figure 5). Majka et al. teach the CD34+ are haemotopoietic cells of the bone marrow which are involved angiogenesis as evidenced by Peichev et al. (see page 957, column 2).

Thus, Majka et al. anticipates claims 1-6 of the instant application.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Peichev et al. (cited on PTO form 1449 filed 7/22/2004).

The instant claims are drawn to a method of screening for molecules for the treatment of pathological angiogenesis comprising exposing prominin-1 or nucleic acids encoding prominin-1 to at least one molecule and determining binding or hybridizing of said molecule and monitoring said pathological angiogenesis.

Peichev et al. teach a method of determining the biological effect of AC133 (also called prominin) comprising exposing CD34+ cells expressing AC133 to antibody against AC133 and measuring the binding of the antibody to AC133 wherein the cells are immobilized on plates (see page 955). Peichev et al. further teach monitoring of the CD34+ cells ability to form endothelial cell monolayers and teach CD34+ expressing AC133 are involved angiogenesis (see page 957, column 2).

Thus, Peichev et al. anticipates claims 1-6 of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peichev et al. (cited on PTO form 1449 filed 7/22/2004) and Majka et al. (cited on PTO form 892 filed 12/19/2005) in view of Babinet et al. (An. Acad. Bras. Cienc. 2001) and in further view of Murphy et al. (US 2003/0045489).

The instant claims are drawn to a method of screening for molecules for the treatment of pathological angiogenesis comprising exposing prominin-1 or nucleic acids encoding prominin-1 to at least one molecule whose ability to suppress or prevent pathological angiogenesis is sought to be determined, determining binding or hybridizing of said molecule and monitoring said pathological angiogenesis when administering said molecules as a medicament. The claims are further drawn to a method of screening for the treatment of pathological angiogenesis comprising identifying molecules that inhibit the expression and/or activity of prominin-1 and monitoring said pathological angiogenesis when administering said molecules as a medicament wherein the molecules are identified by providing a mammalian knockout model that does not express prominin-1 and administering said molecule to be tested and wherein the mammal is a mouse and further wherein the model simulates a disease or condition comprising pathological blood vessel formation.

Peichev et al. teach a method of determining the biological effect of AC133 (also called prominin) comprising exposing CD34+ cells expressing AC133 to antibody against AC133 and measuring the binding of the antibody to AC133 wherein the cells are immobilized on plates (see page 955). Peichev et al. further teach monitoring of the CD34+ cells ability to form endothelial cell monolayers and teach CD34+ expressing AC133 are involved angiogenesis (see page 957, column 2). Peichev et al. does not teach a mammalian knockout model for the identification of molecules that inhibit expression or activity of prominin-1. Similarly, Majka et al. teach a method of determining the biological effect of AC133 (also called prominin) comprising administering an antisense oligonucleotide molecule to CD34+ cells expressing AC133 and determining the hybridization of the antisense oligonucleotide to the nucleic acid expression AC133 (see page 58 and Figure 4). Majka et al. teach exposing cells expressing AC133 to antibody against AC133 and measuring the binding of the antibody to AC133 in a FACS assay (see Figure 1) wherein the antibody is immobilized on beads (see page 54 and Figure 1). Majka et al. further teach monitoring of the CD34+ cells ability to form haemotopoietic colonies after treatment with an antisense oligonucleotide targeted to AC133 (see page 58 and Figure 5). Majka et al. teach the CD34+ are haemotopoietic cells of the bone marrow which are involved angiogenesis as evidenced by Peichev et al. (see page 957, column 2). Majka et al. suggest using a knockout model to further elucidate the role of AC133 in the development and function of bone marrow cells (see page 61). Peichev et al. and Majka et al. do not teach a mammalian knockout model.

Babinet et al. teach generation of a knockout mouse model for the study of mammalian biology (see abstract). Murphy et al. teach a mammalian knockout model wherein the mammal is a mouse and teach screening of molecules for the ability to inhibit angiogenesis using the knockout murine model (see paragraph 0166).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a mammalian murine knockout model to screen for molecules for the treatment f pathological angiogenesis.

One would have been motivated to make a knock-out mouse model to identify molecules that modulate AC133 because Peichev et al. and Majka et al. teach methods of identifying the role of AC133 in angiogenesis and further Majka et al. suggest using a knock-out model to further elucidate the function of AC133. One would have been further motivated to make a knock-out model because Babinet et al. teach the use of murine knock-out mice is a common way to study the function of genes and more importantly, a way to study the development of appropriate therapies for specific diseases (see page 366). One would have been motivated to make a knock-out model to screen for molecules that modulate AC133 because Murphy et al. teach knock-out animals that simulate a disease associated with angiogenesis are useful to screen for molecules the have anti-angiogenic properties (see paragraph 0167).

Finally, one would have a reasonable expectation of success because Babinet et al. teach generation of a mammalian knockout model, the steps of which are routine to one of skill in the art. Further, one would have a reasonable expectation of success because Murphy et al. teach use of a mammalian knockout model to simulate a disease

associated with angiogenesis and the use of the model to screen for compounds that modulate angiogenesis.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Kimberly Chong
Examiner
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SEAN McGARRY
PRIMARY EXAMINER
1635